Rejection of Claims 27, 28, 32, 33 and 38 under 35 U.S.C. § 112, first paragraph

The Examiner rejected Claims 27, 28, 32, 33 and 38 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the invention. In particular, the Examiner stated that the invention employs a novel organism which must be obtainable by a method set forth in the specification or otherwise available to the public. The Examiner required a statement that the specific strain was deposited under the terms of the Budapest Treaty and that the strain will be irrevocably and without restriction or condition be released to the public upon issuance of the patent.

As disclosed in the subject application at page 5, lines 18 to 22, *Sphingomonas* sp. strain AD109 has been deposited with the American Type Culture Collection under the terms of the Budapest Treaty and designated ATCC No. 55954 . As required under 37 C.F.R. § 1.808, Applicants state that access to this deposit will be available during pendency of the subject patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R.§ 1.14 and 35 U.S.C. § 122. Applicants further state that, with the exception permitted under 37 C.F.R. § 1.808(b), all restrictions imposed by the depositor on the availability to the public of the deposited biological material will be irrevocably removed upon the granting of the patent.

Claims 2, 4, 6, 8 and 46-53 under 35 U.S.C. § 112, first paragraph

Claims 2, 4, 6, 8 and 46-53 stand rejected under 35 U.S.C. § 112, first paragraph, as being drawn to subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains to make or use the invention. In particular, the Examiner stated that the specification is not enabling for claims drawn to nucleic acids encoding mutants, fragments or homologues of the polypeptides described by SEQ ID NO: 2, 4 and 6. According to the Examiner, Claims 2, 4, 6, 8 and 46-53 encompass nucleic acid molecules encoding an extremely large number of mutants, fragments and homologues of SEQ ID NO: 2, 4 and 6. The Examiner further stated that at the time the invention was made, one of ordinary skill in the art could produce any mutant, fragment or homologue of the disclosed sequences, but that, in the absence of structural or sequence homology information, it is not possible to predict the

effects of amino acid changes on protein function. The Examiner supported the rejection by reference to In re Wands, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988) and provided an analysis of the claimed subject matter with respect to the eight factors enunciated by the Court in Wands, namely (1) the quantity of experimentation necessary, (2) the amount of guidance provided, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability of the art and (8) the breadth of the claims.

As discussed above, Claims 2, 4, 6, 8 and 46-53 have been amended to recite that the nucleic acid molecule encodes the enzyme set forth in SEQ ID NO: 2, 4 or 6, or an active fragment or active homologue thereof. The claims further restrict the homologue to sequences having at least about 80% sequence identity with one of the disclosed sequences. With respect to factor 8, above, these amendments more clearly define the scope of the nucleic acid sequences encompassed by these claims.

With respect to factor 2, the specification provides substantial guidance with respect to which amino acid residues can be substituted with probable retention of activity. Figures 8, 9 and 10 compare the amino acid sequences of the DszA, DszB and DszC enzymes from *Rhodococcus* and *Sphingomonas*. One skilled in the art would understand that residues which are conserved in these organisms are likely to be more important for activity than non-conserved residues. The specification, thus, teaches one skilled in the art which residues can be substituted to provide homologues likely to retain enzymatic activity. For example, Figure 8 compares the amino acid sequences of DszA from *Rhodococcus* and *Sphingomonas*. Of the 453 residues in each of these sequences, 343 are identical. One skilled in the art would expect that substitution of one or more of the 110 residues in SEQ ID NO: 2 which are not conserved in the *Rhodococcus* DszA sequence would have less impact on enzyme activity than replacement of one or more of the conserved residues. Further, one skilled in the art would expect homologues resulting from conservative substitution of one or more residues to exhibit greater activity than sequences resulting from non-conservative substitutions.

With regard to factors 5 and 6, the Examiner stated that one of ordinary skill in the art could produce any mutant, fragment, or homologue of the disclosed amino acid sequences. This

ability enables one skilled in the art to prepare a variety of proteins having sequences homologous to those set forth in SEQ ID NO: 2, 4 and 6 without undue experimentation. This ability, coupled with the guideposts provided by the specification with respect to functionally important residues, would clearly enable one skilled in the art to readily identify a large number of sequences that would be expected to exhibit enzymatic activity. Further, the desired enzymatic activity can be assessed by routine screening.

As established by the foregoing discussion, Applicants' claimed subject matter is supported by an enabling disclosure as required under 35 U.S.C. § 112, first paragraph. Reconsideration and withdrawal of the rejection on this basis are respectfully requested.

Rejection of Claims under 35 U.S.C. § 112, second paragraph

The Examiner rejected Claims 3, 5, 7 and 24-39 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants view as the invention. In particular, the Examiner indicated that these claims are rendered vague and indefinite by the phrase "substantially the same".

Claims 3, 5, 7, 24, 28, 29, 34, 35 and 39 have been amended to delete the term "substantially the same" or "substantially". Claims 25-27, 30-33 and 36-38 each depend from one of Claims 24, 28, 29, 34 and 35. These amendments, thus, obviate the rejection on this basis.

Rejection of Claims 28, 34 and 39 under 35 U.S.C. § 102(b)

Claims 28, 34 and 39 stand rejected under 35 U.S.C. § 102(b) based upon a public use or sale of the invention. In particular, the Examiner stated that these claims, which are drawn to fragments of any length of the polypeptides described by SEQ ID NO: 2, 4 and 6. According to the Examiner, these fragments are not limited to enzymatically active fragments, and the claims, therefore, read on any of the naturally occurring amino acids.

As discussed above, Claims 28, 34 and 39 have been amended to limit the claimed fragments to enzymatically active fragments. These amended claims do not read on a single amino acid and are not anticipated under 35 U.S.C. § 102(b). Reconsideration and withdrawal of the rejection are respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned at (781) 861-6240.

Respectfully submitted,

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